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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/114,810	07/13/1998	ANTHONY ATALA	CME-117	9691

7590 01/27/2004

LAHIVE AND COCKFIELD
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BOSTON, MA 02109

EXAMINER	
RODRIGUEZ, CRIS LOIREN	
ART UNIT	PAPER NUMBER
3763	

DATE MAILED: 01/27/2004

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/114,810	ATALA ET AL.	
	Examin r	Art Unit	
	Cris L. Rodriguez	3763	

-- The MAILING DATE of this communication appears on the cover sh et with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 November 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *55-91* is/are pending in the application.

4a) Of the above claim(s) *55-63,65 and 68-78* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *64,66,67 and 79-91* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *07 November 2003* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Newly amended claim 56 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: a restriction requirement was made on paper No. 5 filed on September 23, 1999, and applicant elected Group I, species A)figures 1-3 without traverse. Since claim 56 can be grouped in the non-elected invention (group II), therefore is withdrawn from consideration by the examiner.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 56 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

2. Applicant is reminded of its election of Group I, species A)figures 1-3 without traverse in Paper No. 8. Applicant's arguments are not convincing for the reasons herewith. Applicant's disclosure set forth distinct and independent inventions, and several applications of the different inventions; i.e. erectile dysfunction, muscle inflammation and hair loss. Therefore, it would have been a burden for the examiner to search for the different inventions and its uses. Moreover, the search for an apparatus claim is not the same for a method claim.

The requirement is still deemed proper and is therefore made FINAL.

Drawings

3. The drawings are objected to because proposed drawing correction contain two figures of Figure 10; one has been approved, and the other that has the transversal cut line has been disapproved because that transversal cut should have been shown in one corrected Figure 10 with all the other proposed corrections. Correction is required.

4. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the device comprising a battery as set forth in claim 80 for the elected species must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claim 91 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. All the therapeutic agents in claim 91, except from minoxidil, are disclosed for hair loss treatment and not for penile tissue.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 64, 66, 67, 79, 80, 81, 82, 84-88 are rejected under 35 U.S.C. 102(a) as being anticipated by Eppstein (US 6,527,716).

Eppstein discloses a therapeutic drug delivery device (Fig. 28) including an applicator, an ultrasound transducer, a controller for varying the frequency and power of the ultrasound energy, and a detector for monitoring feedback signals from the transducer (col. 41, and 54). The intended use has not been given patentable weight.

9. Claims 64, 66, 67, 79, 80, 81, 89, and 91 are rejected under 35 U.S.C. 102(b) as being anticipated by Henley (us 5,538,503).

Henley discloses a therapeutic drug delivery device including an applicator 10, an ultrasound transducer 11, a controller for varying the frequency and power of the ultrasound energy, and a detector for monitoring feedback signals from the transducer

and 54). The intended use has not been given patentable weight. The device can deliver several kind of drugs I.e. minoxidil.

10. Claims 64, and 79-83, and 85-88 are rejected under 35 U.S.C. 102(e) as being anticipated by Ogden (US 5,656,016).

Ogden discloses a therapeutic drug delivery device comprising an applicator 12, an ultrasound transducer, and a detector for monitoring feedback signals from the transducer (col. 4, lines 17-23). The intended use has not been given patentable weight, since the device can be used in other parts of the body.

11. Claims 64, 66, 67, 80, and 81 are rejected under 35 U.S.C. 102(e) as being anticipated by Bock (US 5,618,275).

Bock discloses an ultrasonic device having an applicator, 1,2,3 and an ultrasound transducer. The intended use has not been given patentable weight.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. Claim 90 is rejected under 35 U.S.C. 103(a) as being unpatentable over Henley in view of Neal (US 6,103,765).

Henley discloses the invention substantially as claimed. Henley's device can deliver several kind of drugs I.e. minoxidil. However, Henley fails to disclose the use of specifically a phosphodiesterase type-5 inhibitor such as sildenafil or alprostadil.

Neal teaches the use of sildenafil as a topical medicament. Given the teachings, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use Neal's sildenafil with Henley's device as an alternative way of topical drug delivery, since Henley is capable of delivering other drugs.

Response to Arguments

14. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

15. The claims do not have enough structural language to anticipate the references.

16. In response to applicant's argument that applicant's claims are for promoting transdermal absorption of a therapeutic agent to a penile tissue, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Conclusion

17. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Unger, Redano, Hoffman et al, and Wirt.

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cris L. Rodriguez whose telephone number is (703) 308-2194. The examiner can normally be reached on 7:30 am - 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (703) 308-3552. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

January 16, 2004

Cris L. Rodriguez
Examiner
Art Unit 3763

BRIAN L. CASLER
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700